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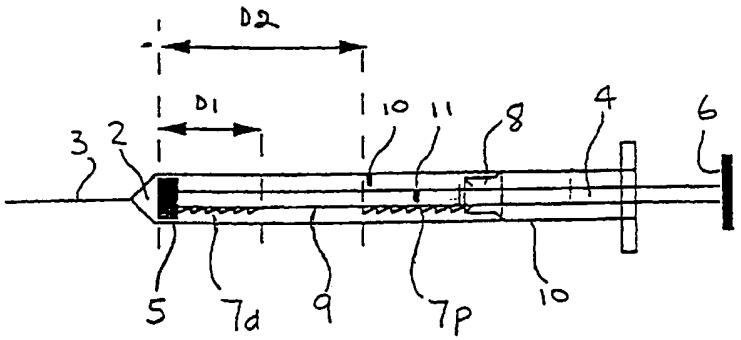

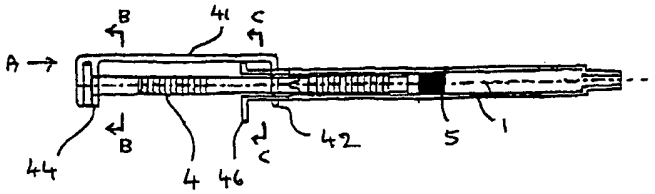

(57) Abstract: A restricted use syringe which allows two aspirating strokes and two discharge strokes. Within the barrel a piston is movable by a plunger rod. The plunger rod has blocks of non-return elements separated by a portion without non-return elements. On the plunger rod is a locking member with a non-return member which engages the side wall of the barrel and the non-return elements on the plunger rod. The alternating blocks and non-return elements interact with the locking member to allow two aspirating strokes and two discharge strokes, so the syringe can be used to administer lyophilised vaccines, but thereafter to be non re-usable. A stroke limiter device suitable for use with the syringe is also disclosed.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

RESTRICTED USE SYRINGE

This invention is concerned with a hypodermic syringe having a locking device which prevents further use of the syringe after the intended administration of a single dose to a patient. Such a locking device can for example help to prevent unauthorised subsequent re-use of a used hypodermic syringe, e.g. by substance abusers etc.

There have been many proposals for simple devices to convert inexpensive plastic hypodermic syringes into single use syringes that are difficult to reuse. A problem with most of these devices is that they require a specific action by the user to lock the syringe against further use, or else they cannot be implemented in syringes of small barrel capacity.

Examples of such non-reusable syringes are for example disclosed in US-A-5,059,181 (Agran), US-A-5,250,030 (Corsich), US-A-5,328,476 (Bidwell), US-A-5,733,261 (Obong) and EP-A-0 339 954 (Syntrall Canada Inc.).

A particularly useful device which avoids these problems is disclosed in US-A-5,531,691 and US-A-5,562,623 of David Shonfeld and Joel Schoenfeld (assigned to Univec, Inc.). The disclosure of both these patents is hereby incorporated herein by reference.

A similar system is disclosed in US-A-5,222,942 and EP-A-0 412 968 of Mohandes Bader (Bader und Partner Medizintechnik). The disclosure of both these patents is also incorporated herein by reference.

The Univec device comprises a conventional syringe barrel with needle holder and internal piston, but uses a plunger rod which is formed with a longitudinally extending array of non-return elements (or ratchet teeth). The ratchet teeth are suitably provided as a series of linked frusto-conical formations integrally made with the plunger rod, connected apex to base, with the respective apexes pointing towards the proximal end of the barrel i.e. opposite to the distal end of the barrel which carries the injection needle. Mounted on the plunger rod is a special locking spring clip which expands radially to ride over the ratchet teeth when the plunger rod is moved towards the proximal end of the barrel, and has projections which engage the ratchet teeth when the plunger rod is moved in the opposite direction. The spring clip also has projections which contact the interior side wall of the barrel and provide a frictional grip on the side wall when the plunger rod is moved towards the proximal

end of the barrel, but which slide against the side wall when the plunger rod is moved in the opposite direction.

As a result, the plunger rod is free to move through the spring clip toward the proximal end of the barrel, while the locking spring clip remains stationary relative to the sidewall because of the frictional engagement against the sidewall. In contrast, a reverse movement of the plunger rod towards the distal end of the barrel causes the locking spring clip to lock against the ratchet teeth, so the clip moves with the plunger rod toward the distal end.

Accordingly, the interaction of the plunger rod, barrel and locking spring clip permits the user of the syringe to draw in liquid into the barrel by movement of the plunger rod to pull the piston towards the proximal end. During this movement the radial flexing of the spring clip over the ratchet teeth allows movement of the plunger rod relative to the spring clip. Subsequent movement of the plunger rod and piston toward the distal end of the barrel expels the liquid through the needle but locks the spring clip on the plunger, moving the spring clip to the distal end of the barrel. Any attempt to make a second movement of the plunger rod towards the proximal end of the barrel is prevented by frictional engagement between the spring clip and the sidewall.

Another advantage of this syringe is that the intake volume of the barrel is defined by the predetermined initial location of the locking spring clip on the plunger rod.

The Bader syringe similarly provides ratchet teeth on the plunger rod, but the above referenced patents indicate that the ratchet teeth may be directed up or down the length of the plunger rod, so as to provide a non-return action on either stroke of the rod, as desired. In the Bader device, the locking action is provided by a collar on the plunger rod. The collar has tongue portions that engage or ride over the ratchet teeth, depending on the direction of movement of the plunger rod, and a peripheral surface that frictionally engages the interior side wall of the barrel. When the ratchet effect is in the opposite direction to the above-mentioned Univec device, then the locking collar moves towards the proximal end of the barrel during use of the syringe.

However, a problem with the Univec and Bader devices is that the single use restriction makes the syringe unsuitable for use with liquid medicaments which are reconstituted from freeze-dried material, such as lyophilised vaccines. With such medicaments, it is necessary for the user to draw a measured volume of a diluent into

the syringe from a sealed vial, to inject the diluent into a vial containing the reconstitutable medicament, then to re-draw the liquid medicament back into the syringe, and finally to expel the medicament during injection into a patient. To accommodate such procedure, a two-time use syringe is required.

A multi-use function can be achieved with the existing Univec or Bader syringes simply by extending the length of the barrel and performing several short strokes as the locking clip or collar works its way down or up the plunger rod. However, additional barrel length is usually already provided to allow extra stroke length to compensate for operator inefficiency, (for example, when withdrawing 0.5 ml of liquid from a vial, if the operator does not place the needle at the right place to extract all liquid, a stroke length of greater than 0.5 ml may be required). If this allowance is added to the increased length provided for two-time use, the syringe barrel becomes impracticably long. Also, there is the risk that if the operator uses such a syringe for a two-time use with efficient handling, and so does not make use of all of the extra stroke allowance, the discarded syringe is left with sufficient free space that will allow an unauthorised one-time use.

Surprisingly, we have been able to develop a two-time use syringe having a practicable length by a relatively simple structural modification to the single use system disclosed in the Univec and Bader patents.

According to the present invention there is provided a restricted use syringe comprising:

a hollow barrel with an interior sidewall and having a proximal end and a distal end;

a needle or needle holding means at the distal end of the barrel;

a plunger rod having a proximal end and a distal end, the plunger rod being located within the barrel with the proximal end of the plunger rod extending beyond the proximal end of the barrel,

a locking member mounted on the plunger rod, the locking member having at least one plunger rod engaging part and at least one sidewall contacting part;

the plunger rod having a plurality of ratchet teeth, capable of engaging with the plunger rod engaging part of the locking member, extending along its longitudinal axis;

a piston at the distal end of the plunger for aspirating and expelling fluid;

the ratchet teeth, plunger rod engaging part and sidewall contacting part being arranged so that when the plunger rod is moved toward one end of the barrel the locking member holds its position in the barrel as a consequence of the sidewall contacting part engaging the sidewall while the locking member resiliently rides over the ratchet teeth, and when the plunger rod is moved toward the other end of the barrel the plunger rod engaging part engages the ratchet teeth to move the locking member along with the plunger rod,

characterised in that

the plunger rod has along its longitudinal axis alternating length portions with and without ratchet teeth capable of engaging with the plunger rod engaging part of the locking member.

The barrel is suitably cylindrical in internal cross section.

The locking member is suitably a member which is capable of movement only in one direction, i.e. either proximal-toward-distal or distal-toward-proximal along the syringe barrel, under the urging action of the plunger rod as it engages with the plunger rod engaging part of the locking member. The sidewall contacting part(s) of the locking member may prevent movement opposite to this one direction by engaging with the sidewall, e.g. frictionally, by means of barbs, sprung parts etc. The locking member may suitably at least partly surround the plunger rod. The locking member may suitably be a spring clip with projections for respectively engaging the ratchet teeth and sidewall, or the locking member may be a collar having tongues engaging the ratchet teeth and a peripheral surface frictionally engaging the sidewall. Suitable types of locking member are for example disclosed in the above-mentioned US-A-5,531,691, US-A-5,562,623, US-A-5,222,942 and EP-A-0 412 968. A detailed disclosure of a suitable locking member is for example found in US-A-5,531,691 col. 9 line 13 – col. 10 line 52, incorporated by reference. Another detailed disclosure of a suitable locking member is for example found in US-A-5,222,942 col. 9 line 25 – col. 10 line 52, also incorporated by reference. Other constructions of locking member will be apparent to those skilled in the art.

The ratchet teeth capable of engaging with the plunger rod engaging part of the locking member may comprise generally conical or wedge-shaped portions, suitably integrally moulded, of the plunger rod, with the apex of the cone or thin end of the wedge, i.e. the "taper direction" pointing either toward the distal or proximal end. Such teeth and the corresponding plunger rod engaging part of the locking

member may engage by the teeth being able to move relative to the plunger rod engaging part when the teeth move in the taper direction, but when the teeth move in the opposite direction the base of the cone or the wide end of the wedge engage with the plunger rod engaging part, and thereby move the locking member along with the plunger rod. For example the plunger rod engaging part may comprise spring leaves which deflect as the teeth move in the taper direction but which catch against the base or wide end when the teeth move in the opposite direction.

Normally the locking member should be able to move freely in both the distal and proximal directions relative to regions of the plunger rod which do not have such ratchet teeth.

The ratchet teeth may be directed so as to provide a non-return interaction with the locking member, moving the locking member either towards the distal end of the plunger rod or towards the proximal end of the plunger rod. A non-return action moving the locking member toward the distal end may be provided by such conical or wedge shaped teeth having their taper direction pointing in the opposite direction to which the locking member is to move.

In one embodiment, when the ratchet teeth are directed so as to move the locking member only towards the distal end of the plunger rod, then most suitably the alternating sequence of ratchet and non-ratchet portions begins with a block of ratchet teeth adjacent the piston on the plunger rod. This is provided so that at the final stroke of the plunger rod to administer a liquid medicament to a patient, the locking member is in a non-return position adjacent the piston on the plunger rod, and is brought to the needle end of the barrel where it assumes a non-return position relative to the barrel. The result is that the syringe is locked against further use. Further, most suitably the locking member is initially positioned at or adjacent to the proximal end of the block of ratchet teeth furthest away from the piston. This means that the plunger rod immediately becomes engaged with the locking member on the first aspirating stroke of the syringe, so that the syringe is immediately committed to whatever multi-use pattern is designed into its restricted use format. Alternatively, the locking member is already engaged with the ratchet block furthest away from the piston.

In another embodiment, when the ratchet teeth are directed so as to move the locking member only towards the proximal end of the plunger rod, then the situation is reversed and the locking member may be positioned at the distal end of the plunger

rod, on a block of ratchet teeth adjacent the piston. Then on the aspiration strokes the locking member is brought to the proximal end of the cylinder barrel, and at the final stroke of the plunger rod to administer a liquid medicament to a patient, the plunger rod moves through the locking member, leaving it adjacent the proximal end of the cylinder where it is in a non-return position relative to the plunger rod.

In another embodiment the ratchet teeth may again be directed so as to move the locking member only towards the proximal end of the plunger rod. Suitably in such an embodiment, in a longitudinal sequence starting from the distal end of the plunger rod, the plunger rod has three blocks of ratchet teeth, comprising a first block of ratchet teeth, a first length without ratchet teeth, a second block of ratchet teeth, a second length without ratchet teeth, then a third block of ratchet teeth. In this embodiment, in the assembled syringe as provided for use, the locking member is suitably initially positioned with its plunger rod engaging part between the first and second blocks of teeth, preferably adjacent to the proximal end of the first length without teeth.

This last mentioned embodiment is suitable for example for the devices of US-A-5,222,942 in which the locking member is initially located part way between the distal and proximal ends of the syringe barrel.

The syringe of the invention may also be provided with one or more stroke limiter devices to limit the distance the plunger rod may be moved, particularly toward the proximal end of the barrel. For example such a device may prevent the rod from being accidentally pulled completely out of the barrel. When using a syringe it is desirable for the user to limit the distance by which the plunger is withdrawn on the aspiration stroke so that an excessive dose of liquid medicament is not drawn into the syringe barrel. It is especially important in syringes of the above-described type of the present invention in which a locking means eventually locks the plunger against further use to prevent mis-use of the syringe. When such syringes are used in a situation where two strokes of the plunger are required, such as in the solubilisation ad injection of lyophilised vaccines, limiting the stroke can avoid a situation where the plunger becomes locked before completion of the second stroke, because of over-extension on the first stroke. If for example there is a partially indented plunger, there is no reference limiting the first stroke, and if first stroke length is exceeded, the remaining stroke is insufficient for the operation of the second re-aspiration, jeopardising the whole process. A mark on the syringe could be considered as a

alternative to the stroke limiter, but this is less effective than a physical abutment as provided by a stroke limiter device.

Such a stroke limiter may for example comprise a part that projects into the path of the piston or locking member to abut against the piston or locking member if they are moved too far in the proximal direction. For example a stroke limiter may comprise a part which projects into interior of the barrel to obstruct movement of the rod, for example by abutting against the piston or locking member. Suitably such a stroke limiter may be removable from the barrel to thereafter allow subsequent further movement of the plunger rod. For example the stroke limiter may project through an aperture in the sidewall, being insertable and removable via such an aperture. Suitably such a stroke limiter may be retainable on the barrel by a spring clip around the barrel. Types of stroke limiters for syringes are for example known from WO-A-95/04563, FR-A-035149, US-A-4,962,868, US-A-2,856,925, US-A-4,610,668 among others.

In a further aspect the present invention provides an advantageous type of stroke limiter device, particularly suitable for the syringe of the present invention.

According to this aspect of the invention, there is provided a stroke limiter for a syringe comprising a plunger rod located in a syringe barrel, the stroke limiter having:

an elongate backbone portion which defines the limited length of stroke,

a barrel engaging portion at one end of the backbone portion, for sliding engagement with the barrel,

a stop surface for engagement with a stop surface on the barrel,

a plunger rod engaging portion, for fixed engagement with the plunger rod.

Alternatively, the barrel engaging portion may be configured for fixed engagement with the barrel, and the plunger rod engaging portion configured for sliding engagement with the plunger rod; in which case the stop surface of the stroke limiter is configured for engagement with a stop surface on the plunger rod.

Most conveniently, the arrangement is such that the barrel engaging portion of the stroke limiter is slidable on the barrel, because then the stop surface on the barrel may be a flange (suitably the usually already existing oval flange) at the mouth of the barrel (at the opposite end to the needle end). Also, the barrel engaging portion of the stroke limiter acts as the stop surface of the stroke limiter.

In use of the syringe, the plunger rod is withdrawn from the barrel, pulling the piston within the barrel away from the needle, to draw a liquid into the syringe. Due

to the fixed location of the plunger engaging portion of the limiter on, for example a thumb rest on the end of the plunger rod, the stroke limiter moves with the plunger rod. The barrel engaging portion slides along the barrel until it comes against the stop surface on the barrel, thus limiting the stroke of the plunger. Assuming the stroke has commenced with the pusher against the oval flange, the length of the back bone will correspond to the length of the stroke.

The barrel engaging portion may be a ring slidable on the barrel, with the circumference of the ring secured to the backbone so that the plane of the ring is at right angles to the linear axis of the backbone. Alternatively the barrel engaging portion may be a part circular structure that is slidable on the barrel. Most suitably the part circular structure is a substantially U- or C-shaped resilient clip secured to the backbone so that the plane of the ring is at right angles to the linear axis of the backbone.

The plunger engaging portion may similarly be a ring or clip that is dimensioned to have a firm non-sliding grip on the plunger rod. However most suitably it is one or more projections at the end of the backbone that embrace the thumb rest at the end of the plunger rod so that the limiter moves with the plunger rod. This may be achieved by two arms extending at right angles from the end of the backbone opposite to the barrel engaging portion and dimensioned to lie on either side of the thumb rest. For security of attachment, the arm on the barrel side of the thumb rest may terminate in a part-circular structure that is a snap-fit on the pusher rod. For convenience of use, the arm on the other side of the thumb rest may be a substantially circular button to overlie the thumb rest, to provide for easy manipulation by the user.

The stroke limiter device of this aspect of the invention may conveniently be made of rigid but resilient plastics materials such as polypropylene etc.

The present invention therefore also provides a syringe of the above described type, when fitted with such a stroke limiter device. Such a syringe may be of the type in which the ratchet teeth are arranged to move the locking device only toward the distal end or alternatively only toward the proximal end.

For reconstituting and administering a freeze-dried medicament, in order to allow a two time restricted use, the plunger rod preferably has a block of such ratchet teeth adjacent the piston, a block of such ratchet teeth remote from the piston and a length of plunger rod free of such teeth between the two ratchet blocks.

The advantage of the syringe of the present invention is that it allows for a multiple but restricted use, especially a two time use, including an allowance for extra plunger stroke(s) to cover operator inefficiency without requiring an unreasonably long barrel. For example, a syringe intended for delivering a volume of 0.5ml. of diluent can be provided for reconstituting and administering a freeze dried vaccine, while allowing an additional 0.5ml. additional stroke on both aspiration strokes, with a barrel of overall 2ml. capacity. On the other hand, if the operator is aspirating diluent efficiently and does not use the extra stroke allowance, the syringe is left with a maximum of 0.5ml reusable capacity. This may be achieved by providing a plunger rod with two ratchet portions on either side of a non-ratchet gap portion, each portion having a length equivalent to 0.5ml of barrel capacity. The presence of lengths of the plunger rod without ratchet teeth enable the plunger rod to move short distances in both directions.

The syringe of this invention may advantageously be provided with additional locking/re-use prevention devices as disclosed in the above referenced US patents of Univec and Bader. A deliberate action of the operator after the approved use of the syringe disables the syringe to prevent further use, for example, by breaking or locking syringe parts.

The structure and operation of the syringe of this invention will be understood more fully from the following detailed, but non-limiting, description of an embodiment of the invention, with reference to the accompanying drawings.

In the drawings,

Figure 1 is a longitudinal sectional view of a syringe in accordance with the invention.

Figure 2 is a sequence of longitudinal sectional views of the syringe of Fig. 1 showing positions reached in use to reconstitute and administer a freeze-dried vaccine, namely:

2A. the syringe as supplied;

2B. the position after first aspiration;

2C. the position after using extra stroke allowance;

2D. the position after a re-locking forward stroke;

2E. the position after expelling diluent into vial of freeze-dried vaccine;

2F. the position after aspiration of reconstituted vaccine and diluent;

2H. the position after aspiration of reconstituted vaccine if extra stroke allowance is used;

2G. the position after administration of the vaccine using the extra stroke allowance;

2I. the position after administration of the vaccine without using extra stroke allowance.

Figure 3 is a longitudinal sectional view of another construction of syringe of the invention, showing a sequence of longitudinal sectional views of the syringe at positions reached in use to reconstitute and administer a freeze-dried vaccine, namely:

3A. the syringe as supplied;

3B. the position after first aspiration;

3C. the position after expelling diluent into vial of freeze-dried vaccine;

3D. the position after re-aspiration of reconstituted vaccine and diluent;

3E. the position after de-aeration;

3F. the position at a vein test;

3G. the position after final administration of the vaccine to a patient.

Figure 4 is a perspective view of a syringe with a stroke limiter of the invention attached;

Figure 5 is a longitudinal cross-section of the syringe and stroke limiter shown in Figure 4;

Figure 6 is a similar cross-section but with the plunger withdrawn from the barrel of the syringe;

Figure 7 is an end view in the direction A in Figure 6,

Figure 8 is a cross-sectional view along the line B-B of Figure 6,

Figure 9 is a cross-sectional view along the line C-C in Figure 6.

Figure 10 shows a stroke limiter in use on a syringe.

Referring to the accompanying drawings, Fig. 1 shows a cross-section through a syringe in accordance with the present invention as supplied to the syringe user.

The syringe comprises a cylindrical barrel (1) of nominal 2ml. capacity. At the distal end of the barrel (1) is a needle holder (2) supporting a syringe needle (3). Within the barrel, a plunger rod (4) has a piston (5) at its distal end. The barrel is transparent so that the position of the piston (5) is visible to check against graduations marked on the barrel exterior. The proximal end of the rod (4) extends beyond the proximal end of the syringe barrel (1), terminating in a thumb support (6). The

plunger rod (4) is formed with a plurality of non-return elements, or ratchet teeth (7), suitably frustro-conical elements connected apex to base, with the respective apexes pointing towards the proximal end of the barrel, as disclosed in the above referenced Univec patents.

Mounted on the plunger rod (4) is a locking member in the form of a spring clip (8) which contacts the interior wall of the barrel and the non-return elements of the plunger in such a way that, on an aspirating stroke of the plunger the plunger passes through the spring clip, whereas on an injecting stroke of the plunger, the spring clip locks with non-return elements so that the clip is carried towards the distal end of the barrel with the plunger. At the same time, the spring clip has circumferential elements which grip the side wall of the barrel in a non-return fashion which allows the spring clip to move down the barrel towards the distal end of the plunger on an injecting stroke, but prevents it from moving towards the proximal end of the plunger on an aspirating stroke. All these components may be constructed in accordance with the teaching of the Univec patents referenced above.

The syringe of Figs. 1 and 2 departs from the structure of the Univec syringes in that the non-return elements (7) are provided in discrete blocks (7d,7p) alternating with portions (9) of the rod (4) that have no non-return elements. Thus, in the embodiment shown, the non-return elements are in two blocks; block (7d) is positioned at the distal end of the plunger, and block (7p) towards the proximal end of the plunger. Between the blocks (7d) and (7p) is a section (9) of the plunger rod (4) without non-return elements.

The syringe illustrated is designed for reconstitution and administration of a freeze-dried vaccine using 0.5 ml of diluent. In this situation we find it convenient that the first non-return block (7d), the free space (9) and the second non-return block (7p) are each provided in a length D1 equivalent to 0.5ml barrel capacity. A length D2 corresponds to 1.0 ml barrel capacity. The spring clip (8) is positioned at the proximal end of the ratchet block (7p). Accordingly, as soon as the plunger rod is moved on the first aspiration stroke, the spring clip will engage the non-return elements on the block (7p).

In the syringe illustrated, the plunger rod (4) is free of non-return elements between proximal ratchet block (7p) and the end of the rod at thumb support (6). However, depending on manufacturing convenience, the non-return elements may

continue to the end of the rod so that the spring clip is inextricably in a non-return position when supplied to the user.

The procedure for using the device is illustrated by reference to the sequence of Figure 2.

In the position shown in Fig. 2A, the syringe is in the configuration shown in Figure 1, immediately before use by the operator.

In the position shown in Fig. 2B, the operator has inserted the needle through the septum of a vial of diluent and withdrawn the plunger intending to draw up 0.5ml of diluent into the syringe. The ratchet block (7p) has moved through the spring clip, which remains stationary in the barrel.

In the position shown in Fig. 2C, the operator has made an additional withdrawing stroke of 0.5ml to make up for an inefficient take-up of diluent in position 2. The barrel of the syringe is preferably provided with a distinctive marker, such as a red line (10) on the barrel, to mark the maximum withdrawal of the piston which is allowed during the take-up of diluent. Preferably a corresponding mark (11) is provided on the plunger, becoming visible as the marked area of the plunger exits the proximal end of the barrel. During this extra stroke, the spring clip is on the smooth section (9) of the plunger rod. The operator must not exceed the red marker or else the spring clip will lock on to the ratchet portion (7a), and this will restrict the up-take of the reconstituted vaccine for injection in the later stages.

In the position shown in Fig. 2D, the operator has introduced the needle through the septum of a vial of reconstitutable freeze-dried vaccine, and advanced the plunger rod to begin expelling diluent. This engages the non-return portion (7p) with the spring clip.

In the position shown in Fig. 2E, the spring clip has been carried down the barrel as the operator pressed the piston fully home to expel all diluent into the reconstituting vial. The vial containing the diluent is shaken to disperse or dissolve the freeze-dried vaccine, reconstituting it as a liquid vaccine.

In the position shown in Fig. 2F, the plunger rod has been withdrawn, intending to take up 0.5ml. of the reconstituted liquid vaccine. On this stroke, the spring clip remains stationary relative to the barrel while the smooth portion (9) of the plunger rod passes through it on the withdrawal stroke.

In the position shown in Fig. 2G, the operator has taken an extra stroke to extract all the liquid vaccine from the reconstituting vial, during which the spring clip

has engaged a ratchet portion (7d). If the operator uses the whole of this extra stroke allowance, the piston comes up against the spring clip and no further withdrawal of the plunger rod is possible, since the spring clip cannot move towards the proximal end of the barrel. The syringe is now fully charged for administration of the vaccine, and the vaccine is injected into the patient by advancing the plunger rod.

In the position shown in Fig. 2H, the plunger rod has been pushed fully home to expel all the vaccine, and the spring clip has been carried to the distal end of the barrel so that the syringe cannot be reused.

On the other hand, if the operator does not need the extra stroke shown in Fig. 2G , but has been able to pick up the full 0.5ml. of vaccine at position 6, then injecting the vaccine from that point, will result in the position shown in Fig. 2I where the spring clip is carried to a point which gives a maximum potential withdrawal stroke for unauthorised reuse of 0.5ml. In actual practice, it is unlikely that an operator will achieve a 100% efficient take-up of the diluent, so that the available volume for re-use will almost certainly be less than 0.5ml.

An alternative embodiment of the restricted use syringe of this invention may be constructed substantially as described above, but with the ratchet teeth providing a non-return action in the opposite direction. For example, the ratchet teeth may be frustro-conical formations connected apex to base, but with the respective apexes pointing towards the distal end of the barrel. In that case, in the starting position 2A, the locking member is positioned on the plunger rod adjacent the piston.

The locking member (8) may be a spring clip as in the above referenced US-A-5,531,691 or a collar constructed as in the above referenced US-5,222,942.

Referring to Fig. 3, features in common with Figs. 1 and 2 are numbered correspondingly. A needle (3) is not shown, but the distal end of the barrel (1) of the syringe of Fig. 3 is provided with a needle connector (2) which is connectable to a needle in a conventional manner.

The cylindrical barrel (1) changes diameter at a step (12) approximately half way along its distal-proximal length, being of smaller diameter toward the distal end.

The plunger rod (4) is again formed with a plurality of non-return elements, or ratchet teeth (7), suitably frustro-conical elements connected apex to base, this time with their taper directions pointing towards the distal end of the barrel, as disclosed in the above referenced US-A-5,222,942. The syringe of Fig. 3 departs from the structure of the syringes of US-A-5,222,942 in that the non-return elements (7) are

provided in discrete blocks (7d,7p,7m) alternating with portions (9d,9p) of the rod (4) that have no non-return elements. Thus, in the embodiment shown, the non-return elements are in three blocks, comprising in sequence from the distal end a first block of ratchet teeth (7d), a first length (9d) without teeth, a second block (7m) of ratchet teeth, a second length (9p) without teeth, then a third block (7p) of ratchet teeth.

Mounted on the plunger rod (4) is a locking member in the form of a collar (8), typically constructed as in the above referenced US-5,222,942. Alternatively the locking member (8) may be a spring clip as in the above referenced Univec patents. Collar (8) contacts the interior wall of the barrel (1) and the non-return elements (7) of the plunger in such a way that, on an aspirating stroke of the plunger rod (4) (i.e. movement toward the proximal end) the collar (8) engages with non-return elements (7) so that the collar (8) is carried towards the proximal end of the barrel (1), whereas on an injecting stroke of the plunger (i.e. movement toward the distal end) the non-return elements (7) pass through the collar (8). At the same time, the collar (8) has circumferential elements which grip the side wall of the barrel (1) in a non-return fashion which allows the collar (8) to move up the barrel (1) towards the proximal end of the plunger rod (4) on an aspirating stroke, but prevents it from moving towards the proximal end of the plunger (4) on an injecting stroke.

All these components may be constructed in accordance with the teaching of US-A-5,222,942 referenced above.

It is seen in Fig. 3A which shows the initial configuration of the syringe, that the locking member (8) is located so that its plunger rod engaging part (13), at the distal end of collar (8) is at the proximal end of the length (7d), and on the distal side of the second block of teeth (7m). The collar (8) sits in the step (12).

Also shown in Fig. 3 is a stroke limiter device (14) to limit the distance the plunger rod (4) may be moved toward the proximal end of the barrel (1). The stroke limiter (14) comprises a plastic spring clip removeably mounted around the barrel, which has a part (15) that projects through an aperture (16) in the sidewall of the barrel (1) into the interior of the barrel (1) to obstruct movement of the rod (4) by abutting against the collar (8) as this moves together with the rod (4) toward the proximal end.

The procedure for using the device is illustrated by reference to the sequence of Figs. 3A-3G.

In the position shown in Fig. 3A, the syringe is in the configuration as provided for use, immediately before use by the operator.

In the position shown in Fig. 3B, the operator has inserted the needle (not shown) through the septum of a vial of diluent and has withdrawn the plunger rod (4) intending to draw up a suitable volume of diluent into the syringe barrel (1). The tooth-free length (9d) of plunger rod (4) has moved through collar (8), which remains stationary in the barrel (1), but the ratchet teeth block (7d) are unable to move through collar (8) because of the non-return action, and instead teeth (7d) engage with the collar (8) and move collar (8) toward the proximal end of the barrel (1). The collar (8) is only able to move as far as the stroke limiter (12) in this direction because the collar (8) abuts against the part (15).

In the position shown in Fig. 3C, the operator has inserted the needle (not shown) through the septum of a second vial, containing a lyophilised medicament soluble in the diluent. The thumb support (6) has been depressed, the piston (5) has moved toward the distal end of the barrel (1) and expelled the diluent into the second vial. During this operation the second block (7m) of teeth has moved through the collar (8) without moving the collar (8) in the distal direction.

In the position shown in Fig. 3D, with the needle (not shown) still inserted in the second vial, the operator has removed the stroke limiter (14) from the barrel (1) and drawn the plunger rod (4) in the proximal direction. The teeth (7m) are unable to move through the collar (8) because of the non return action, and engage against the collar (8) and move the collar (8) in the proximal direction. A solution of the medicament in the diluent is thereby drawn into the barrel (1). A second stroke limiter (not shown) might be provided between the aperture (16) and the open proximal end of the barrel (1) to prevent the plunger rod being removed completely from the barrel (1).

In the positions shown in Figs. 3E and 3F, the thumb rest (6) is firstly depressed to move the piston (5) a short distance toward the distal end to expel any air bubbles that may be in the barrel (1). Then the needle (not shown) is inserted into the patient, and the piston (5) moved a short distance toward the proximal end in a conventional vein test. It is seen that at this stage the tooth-free length (9p) is adjacent the surrounding collar (8), and thus the rod (4) is free to move freely in both the proximal and distal directions.

In the position shown in Fig. 3G, with the needle (not shown) correctly inserted into the patient, the thumb rest (5) has been depressed to move the piston (5) to the distal end of the barrel (1), thereby injecting the solution of medicament contained therein into the patient. The block (7p) of teeth have moved through the collar (8). Because of the non-return action the teeth (7p) are unable to move through the collar (8) to allow a further movement of the plunger rod (4) in the proximal direction to thereby draw in more liquid, and also because of the non-return engagement of the collar (8) with the inner surface of the barrel (1) it is not possible to move the collar (8) toward the distal end of the barrel (1). The used syringe is therefore not capable of subsequent re-use.

Referring to Figs. 4 to 9, the stroke limiter is a unitary device based on a rod-like backbone portion (41). At one end of the backbone (41) is a part-circular or horseshoe shaped clip (42) and at its other end a circular pusher (43). The clip (42) is engaged with the barrel (1) of the syringe so that the stroke limiter is longitudinally slidable along the barrel (1). The pusher (43) overlies the thumb rest (6) at the end of the plunger rod (4) of the syringe, so that user pressure on the pusher (43) results in a forward stroke of the plunger rod (4) into the syringe barrel. To ensure that the pusher (43) is maintained in alignment with the thumb rest of the plunger rod (4), a further part-circular clip (44) is formed on a protruding extension of the backbone (41) so as to engage the plunger rod. The pusher (43) and clip (44) effectively act as a jaw (43,44) gripping the thumb rest of the syringe, so that the stroke limiter is in fixed engagement with the plunger rod. A conspicuous mark (M) on the transparent barrel (1) shows the distance the piston needs to be drawn back in the proximal direction to aspirate a selected volume such as 0.5 ml into the barrel.

In use of the syringe as shown in Figs. 5 and 6, the plunger rod (4) is withdrawn from the barrel (1), pulling a piston (5) within the barrel (1) away from the needle (45), to draw a liquid into the syringe. The outward stroke commences with the thumb rest (6) adjacent the oval flange (46) formed at the mouth of the barrel (1), as shown in Fig. 5. Due to the fixed location of the plunger engaging jaw (43, 44) on the thumb rest (6) on the end of the plunger rod (4), the stroke limiter moves with the plunger rod (4). The clip (42) slides along the barrel (42) as shown in Fig. 6, until it comes against the oval flange (46) at the end of the barrel (1), thus limiting the stroke of the plunger rod (4).

Accordingly, the length of the back (41) determines the maximum permissible outward stroke of the plunger rod (4).

The stroke limiter is moulded from a resilient plastics material, so that the clips (42) and (44) are a snap fit onto the barrel (1) and plunger rod (4) respectively. However, it is feasible that the stroke limiter is made from a rigid material and is linked with the relevant parts of the syringe by sliding the barrel (1) and/or plunger rod (4) into the part-circular clips (42, 44). If this sliding assembly is used, then of course the clips may be fully circular rings.

It will be appreciated that a reversal of the relative functions of the clips (42) and (44) is feasible, with the clip (42) being fixedly engaged with the syringe barrel and the clip (44) being slidingly engaged with the plunger rod, and acting as a stop surface (pusher (43) being omitted). Then on withdrawal of the plunger from the syringe barrel, the clip (44) can be engaged by stop lugs (not shown) projecting from the plunger rod. However, the configuration shown in Figs 4 –9 is more convenient for assembly and use, since no modification of the existing syringe is required.

Figs. 7, 8 and 9 respectively show an end view of the pusher (43) looking in the distal direction A indicated in Fig. 4, a sectional view looking in proximal direction B indicated in Fig. 6 through the plunger rod (4) showing the clip (44) and the thumb rest (6), and a sectional view looking in proximal direction C indicated in Fig. 6 through the barrel (1) showing the clip (42) and the flange (46)

Referring to Fig. 10, a stroke limiter device of the type illustrated in Figs. 4-9 is shown in use with a syringe of the type illustrated in Figs. 1 and 2, in a series of sequential positions 10A to 10I as follows:

10A starting position, corresponds to 2A.

10B diluent aspiration, corresponds to 2C

10C,10D transfer of diluent to vial for reconstitution, corresponds to 2D/2E.

10E re-aspiration of 0.5 ml of solution, corresponds to 2F

10F extra re-aspiration, in which the clip (42) of the stroke limiter allows a short proximal movement of the plunger rod (4), until the clip (42) abuts against flange (46), to allow a little more than 0.5 ml of solution to be re-aspirated.

10G de-aeration, as the plunger (5) is pushed back to the 0.5 ml mark.

10H a vein test after insertion of a needle (not shown) into the patient, facilitated by the clip (42) of the stroke limiter allowing a short proximal movement of the plunger rod (4) until the clip (42) abuts against flange (46).

10I final injection step.

Fig. 10 also shows by arrows the movements of the plunger rod (4) involved in reaching each position 10B – 10I.

Claims:

1. A restricted use syringe comprising:

a hollow barrel with an interior sidewall and having a proximal end and a distal end;

a needle or needle holding means at the distal end of the barrel;

a plunger rod having a proximal end and a distal end, the plunger rod being located within the barrel with the proximal end of the plunger rod extending beyond the proximal end of the barrel,

a locking member mounted on the plunger rod, the locking member having at least one plunger rod engaging part and at least one sidewall contacting part;

the plunger rod having a plurality of ratchet teeth, capable of engaging with the plunger rod engaging part of the locking member, extending along its longitudinal axis;

a piston at the distal end of the plunger for aspirating and expelling fluid;

the ratchet teeth, plunger rod engaging part and sidewall contacting part being arranged so that when the plunger rod is moved toward one end of the barrel the locking member holds its position in the barrel as a consequence of the sidewall contacting part engaging the sidewall while the locking member resiliently rides over the ratchet teeth, and when the plunger rod is moved toward the other end of the barrel the plunger rod engaging part engages the ratchet teeth to move the locking member along with the plunger rod,

characterised in that

the plunger rod has along its longitudinal axis alternating length portions with and without ratchet teeth capable of engaging with the plunger rod engaging part of the locking member.

2. A restricted use syringe according to claim 1 *characterised* by a plunger rod having a block of such ratchet teeth at its distal end, and a second block of such ratchet teeth toward its proximal end, so that when the piston is at the distal end of the barrel at least a portion of the second block is within the barrel and adjacent the proximal end of the barrel, and a length of plunger rod free of such teeth between the two ratchet blocks

3. A restricted use syringe according to claim 2 *characterised* by ratchet teeth arranged to move the locking member only towards the distal end of the syringe barrel.

4. A restricted use syringe according to claim 2 or 3, *characterised* by a locking member which is capable of movement only toward the distal end of the syringe barrel

5. A restricted use syringe according to any one of claims 1 to 4 *characterised* in that the plunger rod is positioned so that the piston is at the distal end of the barrel, the ratchet teeth are directed so as to move the locking member only towards the distal end of the plunger rod, and the locking member is initially positioned on the plunger rod within and towards the proximal end of the barrel and adjacent the proximal end of, or engaged with, the or a portion of ratchet teeth remote from the piston.

6. A restricted use syringe according to claim 1 or 2 *characterised* in that the plunger rod is positioned so that the piston is at the distal end of the barrel, the ratchet teeth are directed so as to move the locking member only towards the proximal end of the plunger rod, and the locking member is positioned on the plunger rod adjacent the piston.

7. A restricted use syringe according to claim 1 *characterised* by ratchet teeth directed so as to move the locking member only towards the proximal end of the plunger rod, and in a longitudinal sequence starting from the distal end of the plunger rod, the plunger rod has three blocks of such ratchet teeth, comprising a first block of ratchet teeth, a first length without such ratchet teeth, a second block of ratchet teeth, a second length without such ratchet teeth, then a third block of ratchet teeth.

8. A restricted use syringe according to claim 7, *characterised* by a locking member which is capable of movement only toward the distal end of the syringe barrel

9. A restricted use syringe according to claim 7 or 8 *characterised* in that in the assembled syringe the plunger rod is positioned so that the piston is at the distal end

of the barrel, the ratchet teeth are directed so as to move the locking member only towards the proximal end of the plunger rod, and the locking member is initially positioned with its plunger rod engaging part between the first and second blocks of teeth.

10. A restricted use syringe according to any one of the preceding claims *characterised* by one or more stroke limiter device to limit the distance the plunger rod may be moved.

11. A restricted use syringe according to claim 9 *characterised* in that the stroke limiter device projects into the interior of the syringe barrel and abuts against the locking member as this moves toward the proximal end of the barrel.

12. A restricted use syringe according to claim 9 or 10 *characterised* in that the stroke limiter device is removable from the barrel.

13. A stroke limiter for a syringe comprising a plunger rod (4) located in a syringe barrel (11), *characterised* by:

an elongate backbone portion (41) which defines the limited length of stroke,

a barrel engaging portion (42) at one end of the backbone portion (41), for sliding engagement with the barrel (1),

a stop surface (42) for engagement with a stop surface (46) on the barrel (1),

a plunger rod engaging portion (43,44) for fixed engagement with the plunger rod (4).

14. A stroke limiter according to claim 13 *characterised* in that the barrel engaging portion (42) of the stroke limiter also acts as the stop surface (42) of the stroke limiter by engaging with a flange (46) at the opening of the barrel (1) where the plunger rod (4) enters the barrel (1).

15. A stroke limiter according to claim 13 or 14 *characterised* in that the barrel engaging portion is a ring or part circular structure (42) embracing the barrel (1) and secured to the backbone (41) so that the plane of the (part-circular) ring is at right angles to the linear axis of the backbone (41).

16. A stroke limiter according to claim 15 *characterised* in that the part circular structure is a substantially U- or C-shaped resilient clip (42) that is a snap-fit on the barrel (1).

17. A stroke limiter according to any one of claims 13 to 15 *characterised* in that the plunger engaging portion is a ring or clip (44) that is dimensioned to have a firm non-sliding grip on the plunger rod (4).

18. A stroke limiter according to any one of claims 13 to 17 *characterised* in that the plunger engaging portion is a jaw (43,44) at the end of the backbone (41) that embraces the thumb rest (6) at the end of the plunger rod (4) so that the limiter moves with the plunger rod (4).

19. A stroke limiter according to claim 8 characterised in that the jaw piece (44) on the barrel side of the thumb rest (6) terminates in a part-circular structure that is a snap-fit on the plunger rod (4).

20. A stroke limiter according to claim 18 or 19 *characterised* in that the jaw piece (43) remote from the syringe barrel (1) is a button which overlies the thumb rest (11).

21. A stroke limiter for a syringe comprising a plunger rod (4) located in a syringe barrel (1), the stroke limiter having:

an elongate backbone portion which defines the limited length of stroke,
a barrel engaging portion at one end of the backbone portion, for fixed engagement with the barrel,
a stop surface for engagement with a stop surface on the plunger rod,
a plunger rod engaging portion, for sliding engagement with the plunger rod.

22. A restricted use syringe according to any one of claims 1 to 12, when provided with a stroke limiter device according to any one of claims 13 to 21.

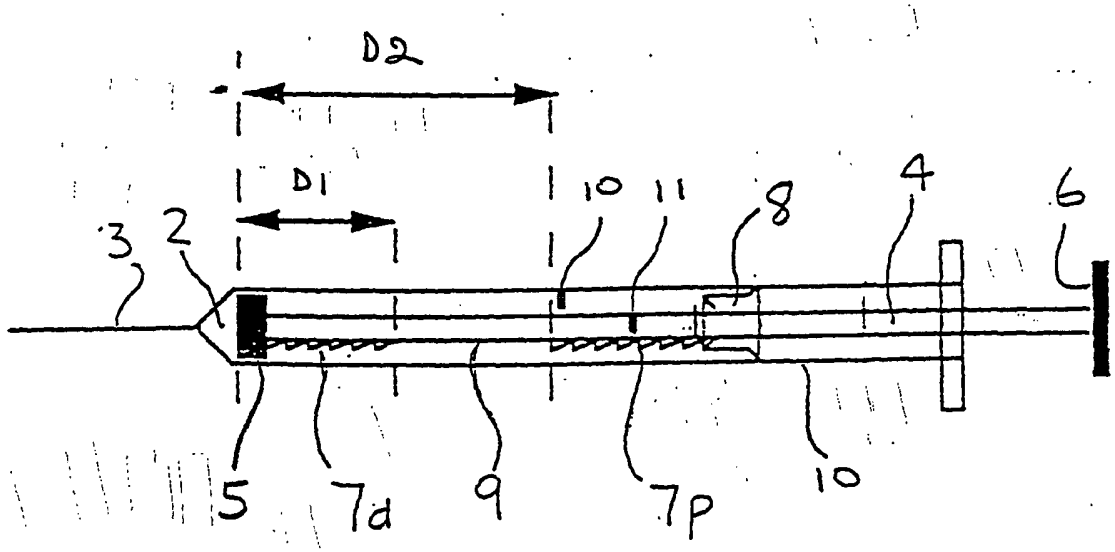

Fig. 1

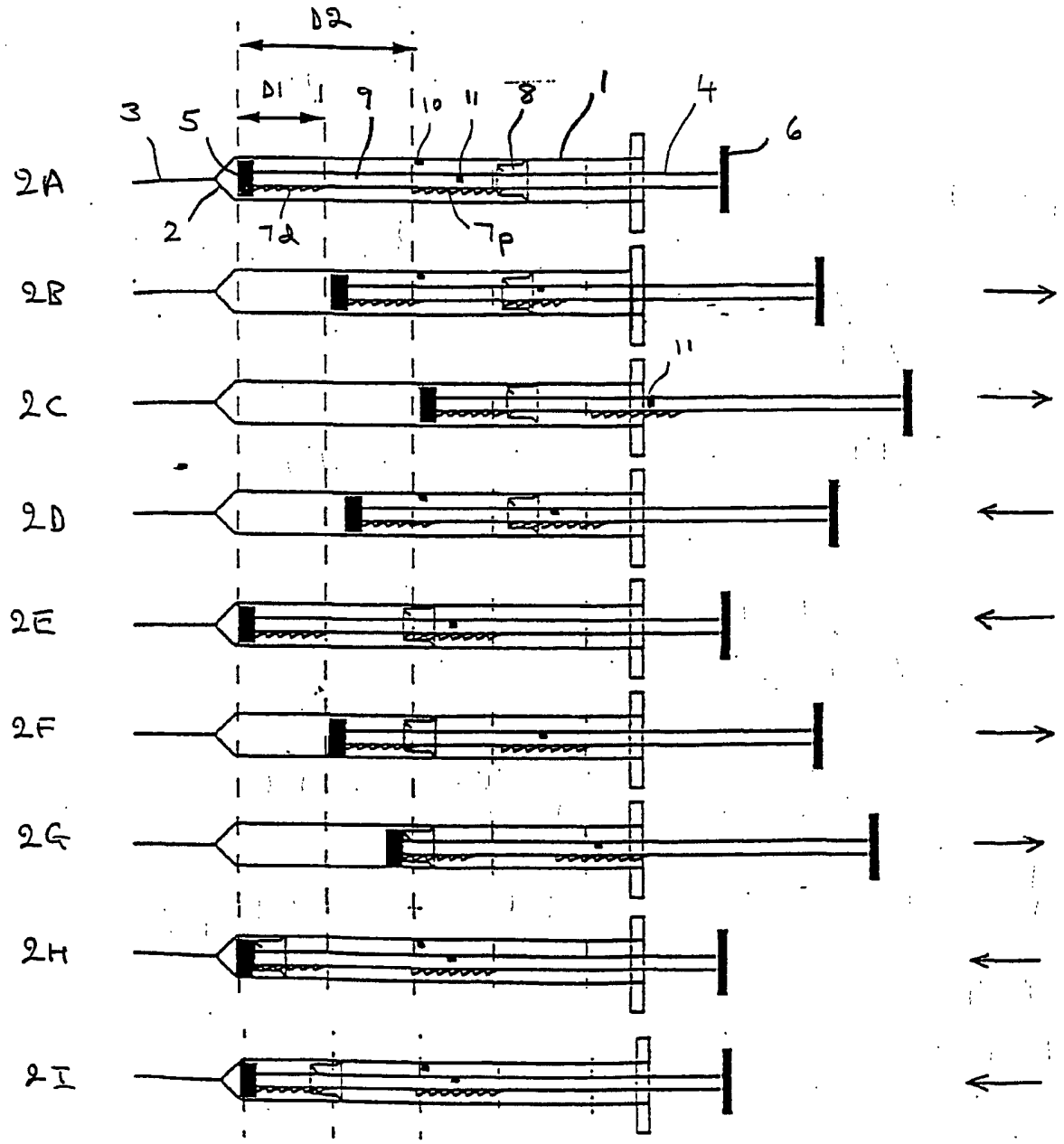

Fig. 2

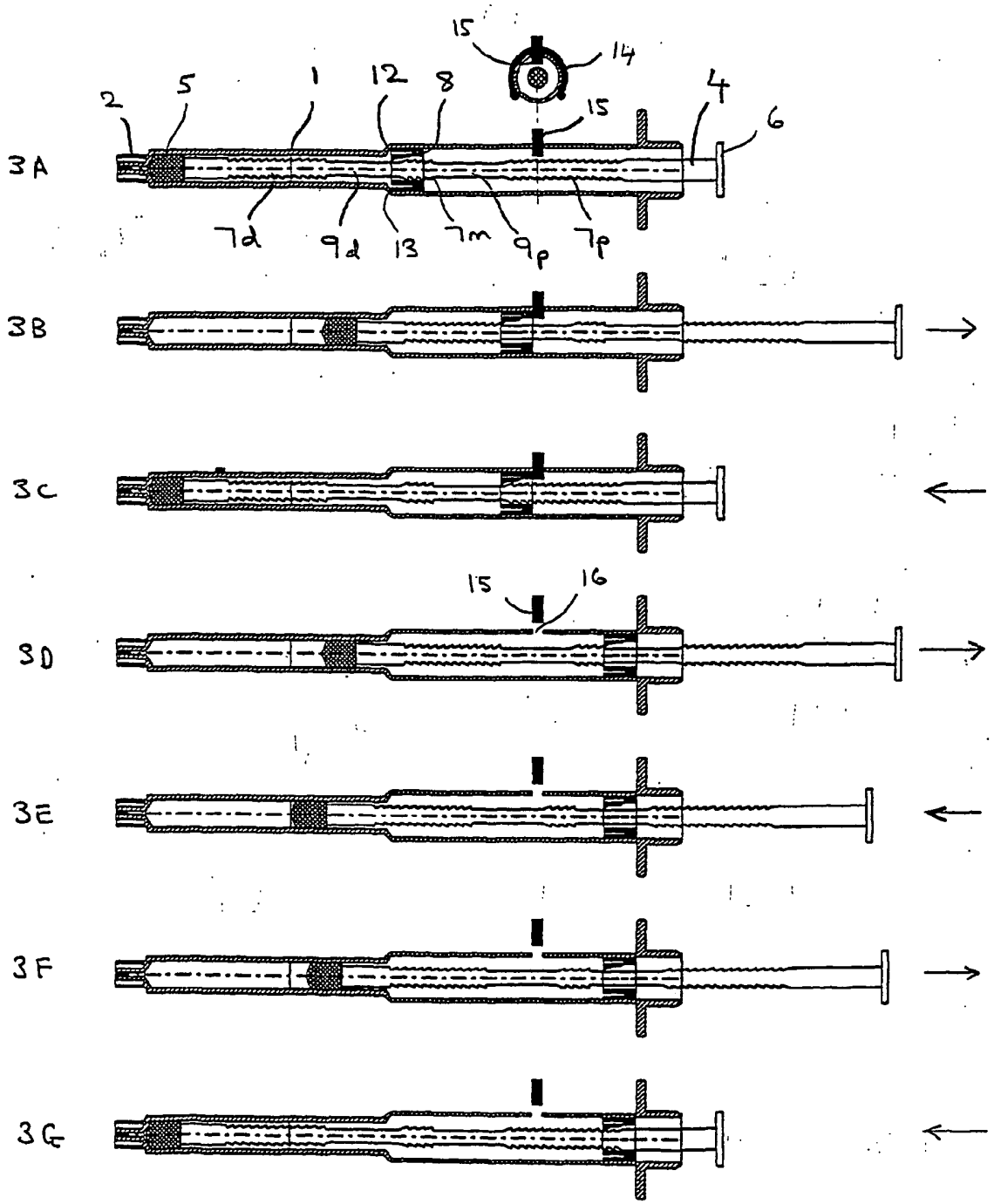

Fig. 3

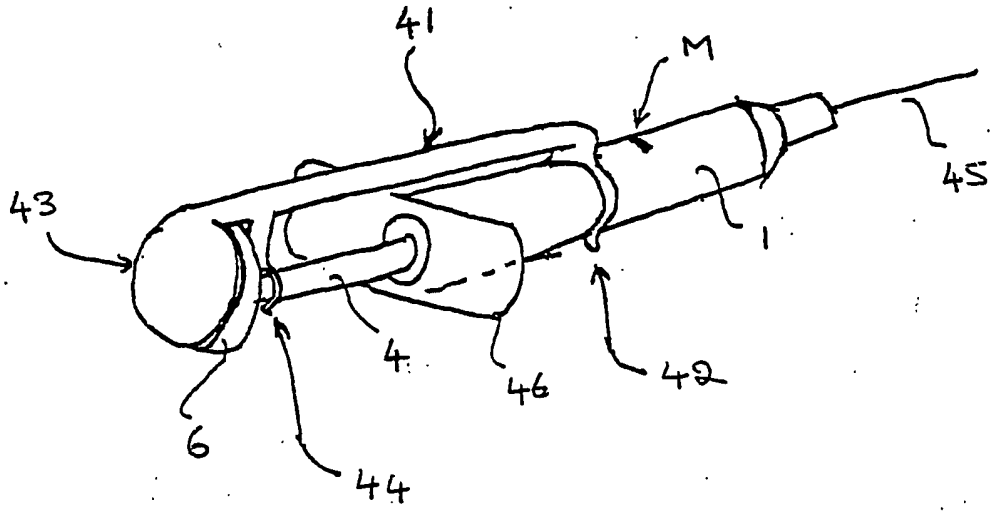

Fig-4

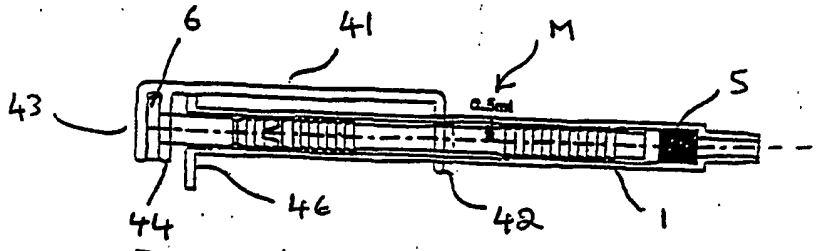

Fig-5

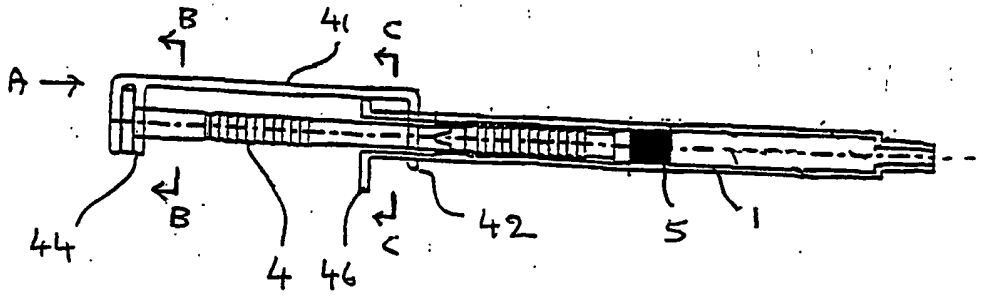

Fig-6

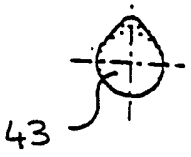

Fig-7

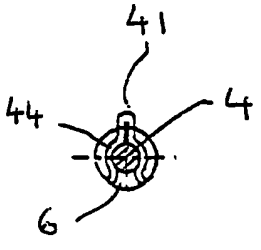

Fig-8

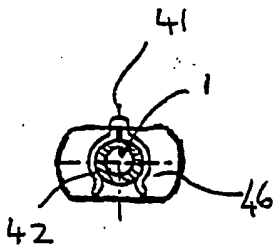

Fig-9

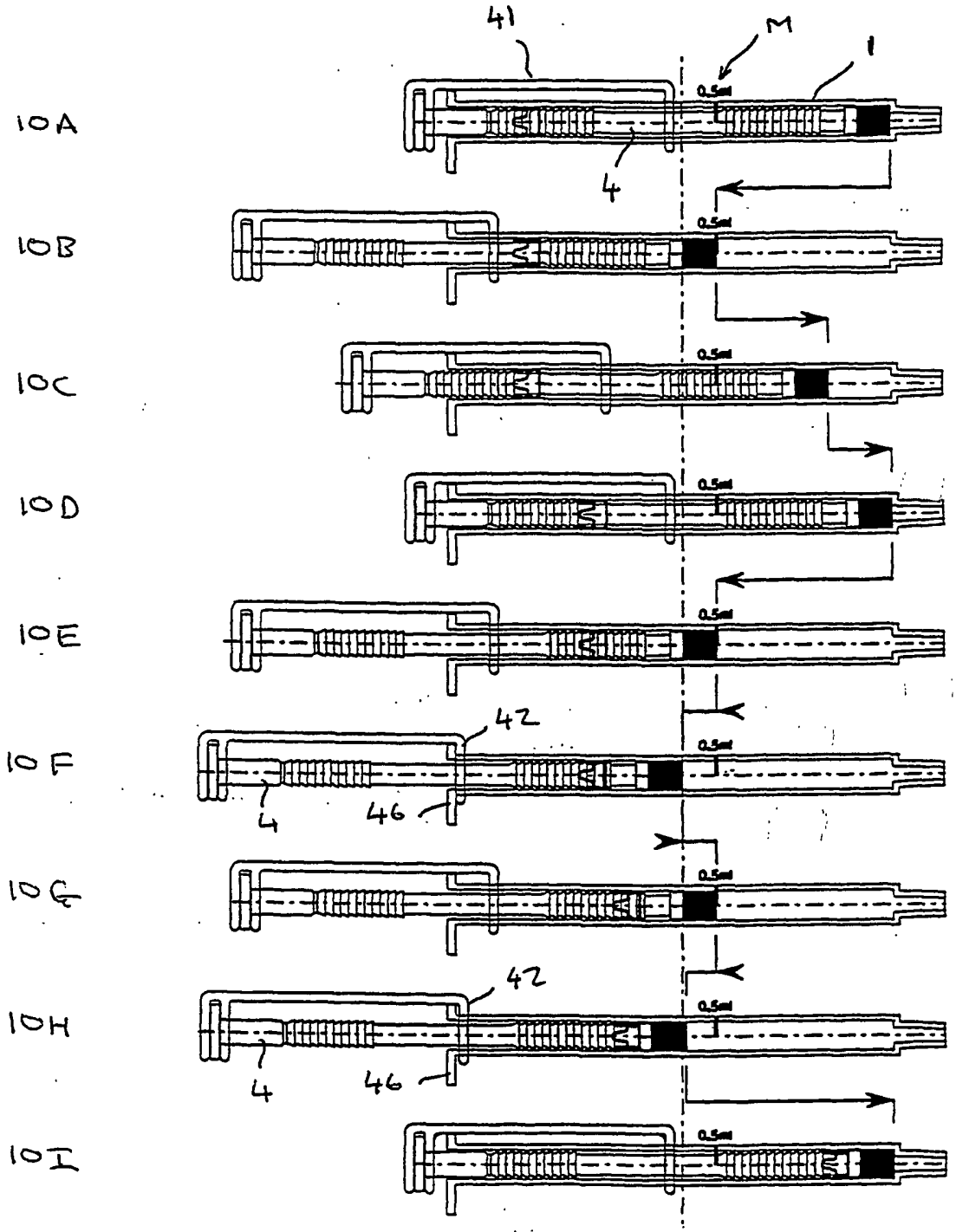

Fig. 10

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/EP 01/04603

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/50 A61M5/315

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 562 623 A (SCHOENFELD JOEL S ET AL) 8 October 1996 (1996-10-08) cited in the application column 15, line 32 - line 67 figures 10,11 ---	4
X	US 4 563 178 A (SANTERAMO JOSEPH J) 7 January 1986 (1986-01-07) the whole document --- -/--	13-15, 17,18,20

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2001	31/08/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Sedy, R

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INTERNATIONAL SEARCH REPORT

Intel ɔnal Application No
PCT/EP 01/04603

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

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